

REMARKS

Reconsideration and withdrawal of the objections to and rejections of the application are requested in view of the amendments and remarks herewith, which are believed to place the application into condition for allowance.

I. STATUS OF CLAIMS AND FORMAL MATTERS

Claims 46-50, 52-56 and 58-78 are pending in this application. By this paper claims 55, 58, 59, 66, 68, and 75 are amended, and claims 52-54 are canceled. Support for the amended claims can be found throughout the specification and from the claims as originally filed. No new matter is added.

It is submitted that the claims, herewith and as originally presented, are patentably distinct over the prior art, and that these claims are and were in full compliance with the requirements of 35 U.S.C. §112. The amendments of and additions to the claims, as presented herein, are not made for purposes of patentability within the meaning of 35 U.S.C. §§§§ 101, 102, 103 or 112. Rather, these amendments and additions are made simply for clarification and to round out the scope of protection to which Applicant is entitled. Furthermore, it is explicitly stated that the herewith amendments should not give rise to any estoppel, as the herewith amendments are not narrowing amendments.

II. OBJECTIONS TO THE CLAIMS

The Office Action objected to claims 52-55 and 65 under 37 CFR 1.75(c), alleging that these claims are of improper dependent form. The Office Action suggests that this objection could be overcome by amending claim 46 read:

"An isolated polynucleotide consisting of 30 contiguous nucleotides of SEQ ID NO:1, or the complement of SEQ ID NO:1, wherein the polynucleotide is DNA, RNA, or PNA, and wherein the polynucleotide optionally consists of i) a moiety that produces a signal, or ii) a binding site for a moiety that produces a signal when the polynucleotide hybridizes to Pseudomonas DNA."

The Examiner suggests that claims 47-50 also be amended similarly. The Examiner is thanked for this suggestion. However, Applicants have chosen not to make such an amendment, as claims 46-50 have already be found allowable. Furthermore, such an amendment would appear to be inconsistent with the statement in the Office Action that the "consisting of" language in claim 46 is "closed, and as such, the nucleic acid molecules of claim 46 can not be added to or changed". The nucleotide sequence of SEQ ID NO: 1 is a DNA sequence, and

therefore does not allow a choice between DNA, RNA, or PNA. For this reason, claims 52, 53, and 54, directed to DNA, RNA, and PNA, have been canceled. In addition, claim 55 has been amended to recite a polynucleotide comprising a polynucleotide according to claims 46-50 and optionally a moiety that produces a signal, or a binding site for a moiety that produces a signal when the polynucleotide hybridizes to Pseudomonas DNA. This amendment is consistent with the Examiner's suggestion and overcomes the rejection of both claim 55, and claim 65 which depends thereupon. Consequently, reconsideration and withdrawal of the objections to the claims under 37 CFR 1.75(c), is requested.

III. THE REJECTIONS UNDER 35 U.S.C. §101 ARE OVERCOME

Claims 58, 61-63, and 68-78 are rejected under 35 U.S.C. §101 as allegedly being directed to non-statutory subject matter. Specifically, The Office Action alleges that the recitation of "determining", "comparing" and "selecting" in claims 58 and 68 is improper, as these terms are used to denote mental steps. By the amendment to claims 58 and 68 presented herein, the rejections of these claims, and the rejections of claims 61-63 and 69-78 that depend thereon, are overcome. Consequently, reconsideration and withdrawal of the rejections under 35 U.S.C. §101 is respectfully requested.

IV. THE REJECTION UNDER 35 U.S.C. §112, 1st PARAGRAPH IS OVERCOME

Claim 75 is rejected under 35 U.S.C. §112, first paragraph, for failing to comply with the written description requirement. The Office Action asserts that while the specification contemplates nucleic acids that are 10-250 nucleotides in length, it does not contemplate nucleic acids that "at least 250 nucleotides" in length. By the amendment to claim 75 presented herein this rejection is overcome. Consequently, reconsideration and withdrawal of this rejection is requested.

V. THE REJECTION UNDER 35 U.S.C. §112, 2ND PARAGRAPH IS OVERCOME

The Office Action asserts that the recitation of "a polynucleotide comprising 10-250 contiguous nucleotides of SEQ ID NO:1" in claims 58 and 59 renders these claims indefinite because SEQ ID NO: 1 is only 131 nucleotides in length. By this paper claims 58 and 59 are amended in accordance with the Examiner's suggestion, thereby overcoming the rejection. The Office Action also rejects claim 66, alleging that the claim is indefinite because it refers to a method, when it should refer to a kit. By the amendment to claim 66 presented herein this

rejection is overcome. Accordingly, reconsideration and withdrawal of the rejections to the claims under this section, is requested.

VI. THE REJECTIONS UNDER 35 U.S.C. §103 ARE OVERCOME

The Office Action rejects claims 68 and 74-78 under 35 U.S.C. § 103(a) as being unpatentable over the combination of (1) Heidrich et al., (2) Rijpkema et al., (3) Jenson et al., (4) Kur et al., and (5) Tyler et al. This rejection is respectfully traversed.

By this paper claim 68 is amended to recite that the primer or probe comprises at least 15 contiguous nucleotides of SEQ ID NO:1. It has already been determined that claims directed to SEQ ID NO:1 are novel and are not obvious in view of the prior art, as evidenced by the Examiner's determination that claim 46 is allowable. Thus, amended claim 68, and claims 74-78 which depend on claim 68, must also be novel and not obvious in view of the prior art.

Applicants assert that claim 68, both as previously presented and in its currently amended form, are not obvious in view of prior art. The fact that the Examiner needs to combine five documents in order to arrive at the teaching of the present invention strongly supports a lack of obviousness of the present claims. Furthermore, it is settled that there must be some prior art teaching which would have provided the necessary incentive or motivation for modifying or combine the teachings of the references in order for an argument regarding obviousness to be made. *In re Laskowski*, 12 U.S.P.Q. 2d 1397, 1399 (Fed. Cir. 1989); *In re Obukowitz*, 27 U.S.P.Q. 2d 1063 (BOPAI 1993). Further, "obvious to try" is not the standard under 35 U.S.C. §103. *In re Fine*, 5 U.S.P.Q. 2d 1596, 1599 (Fed. Cir. 1988). And, as stated by the Court in *In re Fritch*, 23 U.S.P.Q. 2d 1780, 1783-1784 (Fed. Cir. 1992): "The mere fact that the prior art may be modified in the manner suggested by the Examiner does not make the modification obvious unless the prior art suggests the desirability of the modification." Also, the Examiner is respectfully reminded that for the Section 103 rejection to be proper, **both the suggestion of the claimed invention and the expectation of success must be founded in the prior art, and not Applicants' disclosure.** *In re Dow*, 5 U.S.P.Q.2d 1529, 1531 (Fed. Cir. 1988).

The present Office Action picks and chooses aspects of the five cited articles, and asserts that together the combination of these five articles renders the present invention obvious. However, the Office Action fails to specifically state why or how the skilled person would be motivated to combine these five articles to arrive at the teaching of claims 68 and 74-78.

Heidrich *et al.* merely deals with *Legionella*, which is a bacterium unrelated to *Pseudomonas*. The *Legionella* genome is entirely different to that of *Pseudomonas*, and the diseases caused by *Legionella* infection are entirely different to those caused by *Pseudomonas* infection. All of the primers and probes described in Heidrich *et al.* span a region of the 23S-rDNA and 5S-rDNA that is conserved between *Legionella* species, and thus allow genus specific amplification of *Legionella* DNA. Furthermore, Heidrich *et al.* specifically state that their probes do not work with *Pseudomonas* species (col. 16, lines 15-20 and 27). Thus, the skilled artisan would not consider Heidrich *et al.* for combination with the other cited documents in order to reach the claimed invention. On the contrary, Heidrich *et al.* teaches away from the claimed invention.

Similarly, Rijpkema *et al.* deals solely with *Borrelia*, a bacterium unrelated to *Pseudomonas*. The *Borrelia* genome is entirely different to that of *Pseudomonas*, and the diseases caused by *Borrelia* infection are entirely different to those caused by *Pseudomonas* infection. In Rijpkema *et al.*, *Borrelia* specific probes directed to the highly variable 5S-23S rDNA intragenic spacer regions were used in nested PCR. However, the location and sequence of the regions of the 5S-23S rDNA intragenic spacer that can be used to generate species-specific probes is entirely different for every bacterium. Thus, no conclusion as to the sequence or location of *Pseudomonas* specific probes can be drawn from the sequence and location of the *Borrelia* specific probes described in Rijpkema *et al.* In fact, any reliance on the teaching of Rijpkema *et al.* would teach away from the claimed invention.

Jensen *et al.* relates to sequences of the 16S, 23S and 5S ribosomal DNA that are highly conserved among bacteria of different genera, and describes hypervariable spacer regions located between these conserved regions. It is the hypervariable regions, which are entirely different between the bacteria of different genera, which can be used to detect and distinguish between bacteria of different genera. While Jensen *et al.* provides a general description of conserved and highly variable regions in the genomes of various bacterial genera, it fails to teach or suggest the present invention. Jensen *et al.* do not disclose sequences that are useful in distinguishing *Pseudomonas* DNA from DNA of other bacterial species.

In Kur *et al.* 40 clinically distinct strains of *Pseudomonas* were studied using PCR and restriction fragment length polymorphism (RFLP) analysis. However, the skilled artisan does not gain any guidance from Kur *et al.* as to which specific sequences in the variable regions of the

Pseudomonas genome could or should be used for identification of specific *Pseudomonas* species. In particular, Kur *et al.* do not teach or suggest SEQ ID NO: 1, or parts thereof.

Tyler *et al.* teaches sets of primers designed to distinguish between different species of *Pseudomonas*. However, in contrast to the present invention, Tyler *et al.* fail to teach a primer pair that can be used to identify all *Pseudomonas* species. In particular, *Pseudomonas cepacia* could not be detected using the universal primer pair of Tyler *et al.* Tyler *et al.* fails to teach or suggest SEQ ID NO: 1, or parts thereof, and provides no guidance as to which specific genomic sequences should be used for species-specific detection of *Pseudomonas*. Even if the skilled artisan were to use the nucleotide sequences disclosed by Tyler *et al.* he would not arrive at the sequence of SEQ ID NO: 1.

Thus, none of the above references, either alone or in combination, teach or suggest the method of amended claim 68, or of claims 74-78 which depend thereupon. Accordingly, reconsideration and withdrawal of the rejections to the claims under 35 U.S.C. §103 is respectfully requested.

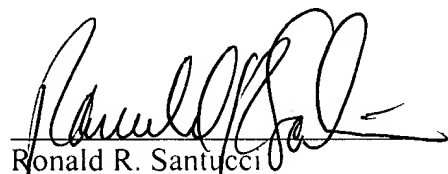
CONCLUSION

Applicants believe that the application is in condition for allowance, and favorable reconsideration of the application and prompt issuance of a Notice of Allowance are earnestly solicited. Alternatively, consideration and entry of this paper are requested, as it places this application into better condition for purposes of appeal.

Respectfully submitted,

FROMMER LAWRENCE & HAUG LLP
Attorneys for Applicant

By:

A handwritten signature in black ink, appearing to read "Ronald R. Santucci", written over a horizontal line.

Ronald R. Santucci
Registration No. 28,988

Samuel H. Megerditchian
Registration No. 45,678